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Taming “Rogue” Pharmacy Websites: The Response to Illegal Prescription Drug Sales on the Internet

Michael Downs

“Two inexorable forces of the 1990s – the growth of the Internet and rapid rise of prescription drug use – appear to be on a collision course.”¹

“The fact is, there a number of sites that are practicing illegally and need to be shut down.”²

I.

Introduction

What has emerged from recent media coverage,³ White House statements,⁴

¹Francine Kiefer, *Online Pharmacies Draw Federal Scrutiny: The Clinton Administration Proposes Rules to Prevent Internet Drug Sale*, CHRISTIAN SCI. MONITOR, Dec. 29, 1999.

²Chris Adams, *Plan to Curb Drugstores on Web Is Hit*, WALL ST. J., Dec. 29, 1999 (quoting Carmen Catizone, Executive Director of the National Association of Boards of Pharmacy).

³See generally Anne Veigle, *Web-based Pharmacies Can Pose Health Hazards*, WASH. TIMES, Apr. 4, 2000; Christine Gorman, *The Web Docs: The Internet Can Fill the Gaps in Your Medical Knowledge. But You Need to Know How to Separate the Good Sites From the Bad*, TIME, Apr. 3, 2000; Lucette Lagnado, *Laetrile Makes a Comeback on the Web*, WALL ST. J., Mar. 22, 2000; Mary Hickey, *The Virtual Pharmacy: Be Careful When You Click*, BUS. WK., Mar. 20, 2000; Virginia Postrel, *Prescription for Trouble*, REASON, Mar. 1, 2000 (reporting that online pharmacies challenge traditional medical models and the regulatory backlash threatens broader Internet freedoms); John Henkel, *Buying Drugs Online: It's Convenient and Private, But Beware of 'Rogue Sites'*, FDA CONSUMER, Jan. 1, 2000.

⁴President's Working Group on Unlawful Conduct on the Internet, *The Electronic Frontier: The Challenge of Unlawful Conduct Involving the Use of the Internet* (last modified April 4, 2000) <<http://www.usdoj.gov/criminal/cybercrime/unlawful.htm>> [hereinafter WORKING GROUP REPORT]; Exec. Order No. 13,133, 64 FR 43,895 (1999).

and congressional hearings⁵ is a fairly clear picture of the threat to public health posed by “rogue” online pharmacies and the obstacles facing state and federal agencies in regulating them. Exactly who should be regulating online pharmacies and what, if any, additional legislation is necessary is less clear. Several different courses of actions have been proposed to address the almost universally perceived threats to public health and the privacy of consumer information.⁶ What is very clear is that nobody is certain how to address the fact that many of these “rogue” online pharmacies are based in foreign countries, and this is cause for serious concern.⁷

The following discussion provides an overview of how online pharmacies operate and what potential risks they pose to public health. It also outlines the laws and authorities that regulate online pharmacies, the obstacles to enforcing existing laws, and recent actions taken against “rogue” websites. Finally, it offers an overview of several different recent proposals designed to meet the challenges of online pharmacies.

II.

Background

⁵*Hearing on E-Drugs: Who Regulates Internet Pharmacies? Before the Senate Comm. on Health, Education, Labor and Pensions*, 106th Cong., March 21, 2000 [hereinafter *Senate HELP Hearing*]; *Hearing on Drugstores on the Net: The Benefits and Risks of On-line Pharmacies Before the Subcomm. On Oversight and Investigations of the H.R. Com. Comm.*, 106th Cong., July 30, 1999 [hereinafter *House Oversight Hearing*].

⁶*See, e.g.*, WORKING GROUP REPORT, *supra* note 4.

⁷*See, e.g.*, Adams, *supra* note 2.

A.

Rapid growth of online pharmaceutical sales

The offering of pharmaceutical products for sale through the Internet is a relatively recent phenomenon. With health care costs on the increase, more consumers are turning to the Internet as a source of health information and as a lower cost source for pharmaceutical products.⁸ According to one recent survey, health concerns are the sixth most common reason people use the Internet.⁹ As a result, during 1999 online pharmacies did more than \$1.9 billion of business in health and beauty products, including prescription drugs, over-the-counter drugs, vitamins, and toiletries.¹⁰ The number of prescriptions being filled online is growing rapidly.¹¹

B.

Benefits of online pharmacies

The benefits of having online pharmacies provide prescription drugs include the convenience and privacy of home delivery and access for those who cannot or choose not to go to a traditional, “brick-and-mortar” pharmacy.¹² Websites also offer health information, buying guides, and direct access to pharmacists.¹³

⁸A 1999 survey by Consumer Reports found that buyers may save up to 29 percent by purchasing certain drugs online. Henkel, *supra* note 3.

⁹*Id.* (citing study by Cyber Dialogue Inc.).

¹⁰*See, e.g.*, WORKING GROUP REPORT, *supra* note 4, at Appendix D.

¹¹In the first two months of its operation, Walgreen Inc.’s Internet pharmacy grew to dispensing 2,000 prescriptions per day. Bruce Japsen, *Clinton Gets Praise for Web Drug Curb Plan*, CHICAGO TRIBUNE, Dec. 29, 1999.

¹²*See, e.g.*, WORKING GROUP REPORT, *supra* note 4, at Appendix D.

¹³*Senate HELP Hearing*, *supra* note 5 (statement of Jane E. Henney, Food and Drug Administration Commissioner). *See also Senate HELP Hearing*, *supra* note 5 (statement of Peter Neupert, chief executive officer of drugstore.com).

Customers may also find lower prices at online pharmacies as a result of price competition among online businesses.¹⁴ It has also been suggested that online pharmacies may help to reduce prescribing errors commonly attributed to poor handwriting and interpretation skills because the prescribing information is transmitted electronically.¹⁵

C.

The trouble with online pharmacies

Some of the websites operating as online pharmacies are cyberspace spin-offs of major American drugstore chains. Others began their businesses online and have already established themselves as legitimate Internet brand names.¹⁶ However, there are many reports of illegitimate domestic and foreign (often appearing to be American-based companies) “rogue” websites that offer low-priced prescription drugs which may be unapproved, counterfeit, contaminated, mislabeled, manufactured in unapproved facilities, or handled improperly.¹⁷

While there have been consumer complaints about these “rogue” websites, with one notable exception¹⁸ there have been few if any serious injuries reported.¹⁹ Nonetheless, the most egregious reported cases make apparent the

¹⁴See, e.g., *Senate HELP Hearing*, *supra* note 5 (statement of Senator James M. Jeffords).

¹⁵*Senate HELP Hearing*, *supra* note 5 (statement of Jane E. Henney, Food and Drug Administration Commissioner).

¹⁶For example, CVS, a well-established drugstore chain, has a pharmacy website at CVS.com. In contrast, drugstore.com started its business in 1999 and only operates in cyberspace. See *Senate HELP Hearing*, *supra* note 5 (statement of Peter Neupert, chief executive officer of drugstore.com).

¹⁷*Senate HELP Hearing*, *supra* note 5 (statement of Senator James M. Jeffords).

¹⁸There was one report of a 52-year-old man with a history of heart disease and episodes of chest pain who died of a heart attack after buying Viagra from an online pharmacy that required only answers to a questionnaire to be approved for the prescription. See Henkel, *supra* note 3 (noting that there is no proof linking the man’s death to the use of the drug).

¹⁹But consumers suffering injuries may be afraid to self-report. *Senate HELP Hearing*,

serious threat to public health posed by these “rogue” websites.²⁰

In fact, there are only six websites, each requiring a valid physicians’ prescription before dispensing prescription medications, that the National Association of Attorneys General (“NAAG”) considers legitimate.²¹ There are over 400 other controversial websites that offer online consultations with a prescriber who then approves the dispensation of desired prescription drugs.²²

The very strengths of Internet technology, including anonymity, speed, and the ability for communications to cross state and international borders, have thus created risks to public health.²³ Suspect websites also present serious challenges to law enforcement because often they are “fly-by-night operations” and “expert at evading detection.”²⁴

Finally, there is “troubling evidence that some health websites may be failing to safeguard the privacy of their customers’ sensitive medical information” and in some cases may even be selling consumer information.²⁵

While these “rogue” online pharmacies are cause for concern, most commenta-

supra note 5 (statement of Calvin A. Anthony, executive vice president of National Community Pharmacists Association).

²⁰In one instance, a journalist received Viagra even after her response to an online questionnaire indicated that she had been “neutered” as the result of a prior surgery. Another journalist was able to acquire a diet drug after indicating on a questionnaire that she weighed only 97 pounds. In a sting conducted by the Kansas Attorney General’s Office, a 16-year-old boy ordered and received Viagra from a website using a credit card in his mother’s name. *Senate HELP Hearing*, *supra* note 5 (statement of Carla J. Stovall, Kansas Attorney General).

²¹*Id.*

²²The Senate Health, Education, Labor, and Pension Committee has received hundreds of reports of Internet pharmacies selling prescription drugs on the basis of answers given to an online health questionnaire and without proof of a physical examination. The American Medical Association has condemned such operations as unethical. *Senate HELP Hearing*, *supra* note 5 (statement of Senator Christopher J. Dodd).

²³*Senate HELP Hearing*, *supra* note 5 (statement of Jane E. Henney, Food and Drug Administration Commissioner).

²⁴Adams, *supra* note 2.

²⁵*Senate HELP Hearing*, *supra* note 5 (statement of Senator Christopher J. Dodd).

tors are also sure to note that any plan to combat the illegal sale of prescription drugs online should not disrupt the societal benefits of online pharmacies and electronic commerce in general.²⁶

III.

Overview of online pharmacies

The websites offering prescription drugs for sale over the Internet may be separated into three distinct categories. The first category includes online pharmacies that operate like traditional “brick-and-mortar” pharmacies or “legitimate” mail-order pharmacies.²⁷ This category includes websites that are the online presence of an established pharmacy chain²⁸ or are relative newcomers that started business in cyberspace.²⁹ Such pharmacies are licensed in each of the states to which they dispense medications and also require that their pharmacists are state-licensed.³⁰ In addition, these pharmacies only fill prescriptions obtained previously by their customers from licensed physicians or transferred from another pharmacy. In either case, these websites attempt to verify the legitimacy of the prescription before filling the order.³¹ These online pharmacies also typically offer a phone number that consumers can call with questions, and

²⁶See, e.g., WORKING GROUP REPORT, *supra* note 4.

²⁷*Id.* WORKING GROUP REPORT, at Appendix D.

²⁸Such a website may be thought of as a “logical extension” of a traditional “brick-and-mortar” or legitimate mail order pharmacy. *Senate HELP Hearing*, *supra* note 5 (statement of Janet Woodcock, Director of the Center for Drug Evaluation and Research of the Food and Drug Administration).

²⁹For example, drugstore.com, which conducts its pharmacy business exclusively through the Internet, was established in 1999. *Senate HELP Hearing*, *supra* note 5 (statement of Peter Neupert, chief executive officer of drugstore.com).

³⁰See, e.g. WORKING GROUP REPORT, *supra* note 4, at Appendix D; Japsen, *supra* note 11 (“Legitimate on-line firms like Drugstore.com Inc. and Planet Rx.com Inc. have state licenses and legitimate contracts with both distributors and drugmakers.”).

³¹*Senate HELP Hearing*, *supra* note 5 (statement of Peter Neupert, chief executive officer of drugstore.com).

some offer health information such as advice on drug interactions.³²

These websites should indicate their licensure in all the states in which they operate, and provide profiles and licensure information for their pharmacists. In short, these websites provide “services you would expect to get from your traditional pharmacy.”³³

Online pharmacies of this type thus conduct business in a manner that suggests compliance with a comprehensive regulatory scheme that includes pre-market approvals, prescription drug designations, practitioner examinations, and pharmacy dispensing.³⁴ Accordingly, this traditional regulatory scheme of state and federal laws constitutes “a safety net to protect the American public from injuries resulting from unsafe drugs, counterfeit drugs, and improper prescribing and dispensing practices.”³⁵

A second and more controversial category of online pharmacies consists of websites that both “prescribe” and dispense prescription medications.³⁶ These websites do not require that a customer already have a legitimate prescription from a licensed physician. Instead, the websites require an online “consultation” before dispensing drugs.³⁷ The customer-patient is asked to fill out and submit

³²*Senate HELP Hearing*, supra note 5 (statement of Janet Woodcock, Director of the Center for Drug Evaluation and Research of the Food and Drug Administration).

³³*Senate HELP Hearing*, supra note 5 (statement of Janet Woodcock, Director of the Center for Drug Evaluation and Research of the Food and Drug Administration).

³⁴See WORKING GROUP REPORT, supra note 4, at Appendix D; *Senate HELP Hearing*, supra note 5 (statement of Jane E. Henney, Food and Drug Administration Commissioner).

³⁵WORKING GROUP REPORT, supra note 4.

³⁶See, e.g., *Senate HELP Hearing*, supra note 5 (statement of Jane E. Henney, Food and Drug Administration Commissioner).

³⁷But often the process is not very rigorous: “[A]ll you have to do is answer a questionnaire and give them your credit card number.” *Senate HELP Hearing*, supra note 5 (statement of Janet Woodcock, Director of the Center for Drug Evaluation and Research of the Food and Drug Administration).

an online questionnaire, specifying medical history, symptoms, and any current medications.³⁸ A prescriber associated with the online pharmacy then supposedly reviews the medical information and approves the desired medication if appropriate.³⁹ Typically, there is a charge for this consultation. Once approved, the pharmacy fills the prescription and ships the product to the customer.⁴⁰ The questionnaires at different websites of this type may vary in the amount and types of information they require, but most ask for information about known allergies, current medical conditions, and current medications.⁴¹ However, many of these sites also provide defaulted or highlighted answers to the medical questions on the online forms, answers that would support a prescription being issued.⁴² One of the more obvious risks in using such a website is “you have no idea whether there’s a doctor in cyberspace who will be evaluating the questionnaire, and you will certainly have no idea of the quality of that doctor.”⁴³ The third category of online pharmacy includes those that dispense prescription drugs without requiring a prescription or online consultation.⁴⁴ Such websites

³⁸WORKING GROUP REPORT, *supra* note 4, at Appendix D.

³⁹*See Senate HELP Hearing, supra* note 5; Naftali Bendavid, *Plan to Regulate Over-the-Web Drug Sales Draws Fire: Clinton Wants the FDA to Monitor Internet Pharmacies, But Some Wonder If the Agency Is Right for the Job*, CHICAGO TRIBUNE, Dec. 29, 1999 (“An estimated 400 Internet sites offer drugs without requiring a prescription from the patient’s physician. Many of these sites have hired doctors who are willing to bend their profession’s rules by writing prescriptions for on-line shoppers without face-to-face contact.”). *See also* Kiefer, *supra* note 1.

⁴⁰WORKING GROUP REPORT, *supra* note 4.

⁴¹*Senate HELP Hearing, supra* note 5 (statement of Janet Woodcock, Director of the Center for Drug Evaluation and Research of the Food and Drug Administration).

⁴²*Id.*

⁴³*Id.* Furthermore, if a patient experiences some side effects after taking the medication, there is typically no health care practitioner he can call with questions or concerns: “[Y]our only recourse is to send the site an e-mail and hope that they respond. It may be that the web site is actually not located within a pharmacy. It may just be a conduit for drug sales. It may take quite a while for a knowledgeable person to contact you, if one ever does.” *Id.*

⁴⁴For the purposes of this discussion, these websites will be referred to as “online pharmacies” although they do not require a prescription. *See, e.g., Senate HELP Hearing, supra* note 5 (statement of Jane E. Henney, Food and Drug Administration Commissioner) (noting that

may offer products making fraudulent health claims, drugs for recreational use, or unapproved drugs.⁴⁵ These websites are clearly in violation of state and federal laws regarding the dispensing of prescription medications.

IV.

Risks of “rogue” websites

A.

The threat to public health

Websites that provide online consultations or issue prescription drugs without requiring prescriptions at all are the focus of the proposed crackdown.⁴⁶ Such operations are likely to be attractive to consumers seeking to purchase so-called “lifestyle” drugs, such as those designed for weight loss, hair loss, or erectile dysfunction.⁴⁷ These drugs are potentially dangerous for certain patients.⁴⁸ However, an online consultation avoids the inconvenience or embarrassment of consulting with a physician in person.⁴⁹ Patients whose physicians

a website dispensing medication without a prescription “may not be a pharmacy at all”).

⁴⁵Typical unapproved drugs offered for sale online include GHB or GBL, the so-called date-rape drugs. *Id.*

⁴⁶These types of websites are the top priority for FDA enforcement efforts. *Id.* The pharmacy industry also considers the “rogue pharmacies” to be those websites both prescribing and dispensing within the same operation. *See, e.g.,* Japsen, *supra* note 11.

⁴⁷*See* Bendavid, *supra* note 39 (“These shady sites are generally powered not by the sale of ordinary drugs, but by demand for such ‘lifestyle’ drugs as Viagra for impotence, Propecia for baldness and Xenical for weight loss.”). A 1999 study by the University of Pennsylvania documented 86 websites selling Viagra without a visit to a physician or a prescription. *See* Kiefer, *supra* note 1.

⁴⁸*See* Japsen, *supra* note 11 (relating how a fifty-three-year-old Chicago man at risk of heart disease died after taking the impotence pill Viagra he ordered through the Internet without first visiting a physician); Bendavid, *supra* note 39.

⁴⁹*See* WORKING GROUP REPORT, *supra* note 4; *Senate HELP Hearing*, *supra* note 5 (statement of Jane E. Henney, Food and Drug Administration Commissioner).

have refused to issue prescriptions for desired medications may easily find an online pharmacy willing to sell them.

Accordingly, websites relying on online questionnaires or dispensing prescription medication without a prescription pose a “significant risk” to public health.⁵⁰ First, transactions conducted in this manner occur outside the “traditional protections” of the doctor-patient relationship.⁵¹ Within this relationship, the risk inherent in prescription drugs may be appropriately managed.⁵² Medications are classified as prescription drugs for the very reason that they are deemed to carry a sufficient risk of side effects, interaction with other medications, or complications caused by other ailments. The prescription system is meant to ensure that a risky medication is not provided to a patient without the involvement of a health care practitioner.

This involvement has traditionally included a physical examination of the patient and medical supervision. Patients traditionally are not expected (or encouraged) to make their own diagnoses and suggestions for medication.⁵³ A physician is relied upon to perform a physical examination because she has the expertise to make a full diagnosis and conduct any tests deemed necessary. A patient’s personal physician can also compile the most accurate medical record

⁵⁰WORKING GROUP REPORT, *supra* note 4, at Appendix D.

⁵¹See *Senate HELP Hearing*, *supra* note 5 (statement of Bruce A. Levy, Executive Director of the Texas State Board of Medical Examiners) (“There is a lack of accountability and there’s health risks.”).

⁵²*Senate HELP Hearing*, *supra* note 5 (statement of Jane E. Henney, Food and Drug Administration Commissioner).

⁵³WORKING GROUP REPORT, *supra* note 4 (“[The Federal Food, Drug, and Cosmetic Act] relies largely on two health professionals – a physician and a pharmacist – to protect patients from the knowing or accidental misuse of medicines that are toxic or that have the potential for causing harm.”).

and provide for follow-up.⁵⁴

The “rogue” online pharmacies issue prescriptions in the absence of these measures. As a result, patients are more likely “to receive an inappropriate medication or to remain un- or misdiagnosed.”⁵⁵

A second stated failure of these particular categories of online pharmacy in terms of public health is that consumers cannot easily confirm their legitimacy.⁵⁶ For instance, a customer can visit a traditional “brick-and-mortar” pharmacy or doctor’s office, visually assess its facilities and staff, and generally assume that the businesses will still be at that physical location the next day. Online pharmacies, in contrast, may be located overseas, making it difficult or impossible to enforce laws protecting consumers. Furthermore, the inability of consumers to assess the legitimacy of an online pharmacy increases the risk that drugs are placebos, mislabeled, or counterfeit.⁵⁷

B.

Privacy of Consumer Information

The anonymity of the Internet, a characteristic that often helps attract those

⁵⁴*Senate HELP Hearing*, supra note 5 (statement of Bruce A. Levy, Executive Director of the Texas State Board of Medical Examiners).

⁵⁵*Senate HELP Hearing*, supra note 5 (statement of Jane E. Henney, Food and Drug Administration Commissioner). *But see* Kim Barker, *Getting Prescription Drugs as Easy as Pie; Louisiana Doctor Among Those with Web Pharmacies*, NEW ORLEANS TIMES-PICAYUNE, Jan. 30, 2000 (quoting Dr. Marcus Kuypers, a Dallas doctor licensed in Washington and working with a Seattle online pharmacy: “There’s lots of mills where you can go in to a doctor, and he can take such an abbreviated history, you’re in and out in two minutes. . . . Is that safer than something online? We review it in much greater detail. I’m taking 10 or 15 minutes with each person.”).

⁵⁶WORKING GROUP REPORT, supra note 4, at Appendix D.

⁵⁷*See* The White House, *The Clinton Administration Unveils new Initiative to Protect Consumers Buying Prescription Drug Products Over the Internet*, December 28, 1999, <<http://www.fda.gov/oc/buyonline/onlinesalespr.html>> (“Consumers who buy prescription drugs online from illegitimate websites are at risk for adverse effects from inappropriately prescribed medications, dangerous drug interactions, or contaminated drugs.”).

purchasing prescription drugs, threatens the privacy of consumer information: “[S]ome online pharmacies might be nothing more than scams, collecting credit card numbers and cash, but providing no products.”⁵⁸

V.

Combating “rogue” websites

A.

Adequacy of existing laws

1. Federal

Existing federal laws are generally adequate to cover the unlawful sale of prescription drugs over the Internet.⁵⁹ Under federal law, which applies to prescription drugs sold in traditional “brick-and-mortar” pharmacies, by mail-order pharmacies, or through telephone orders, the Internet may be considered as just another means of communication.⁶⁰

a)

Food, Drug, and Cosmetic Act

⁵⁸WORKING GROUP REPORT, *supra* note 4, at Appendix D. *See also Senate HELP Hearing*, *supra* note 5 (statement of Jane E. Henney, Food and Drug Administration Commissioner). (“I think it’s fair to say that consumers, particularly if they’re using one of these more risky sites . . . , leave themselves very vulnerable.”).

⁵⁹WORKING GROUP REPORT, *supra* note 4, at Appendix D. *But see Senate HELP Hearing*, *supra* note 5 (statement of Senator Edward M. Kennedy) (“[E]xisting federal . . . laws have had only limited success in protecting customers.”). Senator Kennedy’s observations might be considered more accurately as critical of the current ability to enforce the laws, and not necessarily the adequacy of the laws to cover the online activity at issue.

⁶⁰WORKING GROUP REPORT, *supra* note 4, at Appendix D.

The federal Food, Drug, and Cosmetic Act (“FDCA”) prohibits the manufacture and distribution of misbranded and adulterated drugs and requires them to be labeled accurately. In addition, drugs must be manufactured and handled so as to prevent contamination or misuse.⁶¹ Under the FDCA, drugs categorized as prescription drugs may be dispensed only by the prescription of a licensed practitioner.⁶²

A prescription drug is “misbranded” if it is not dispensed on a valid prescription.⁶³ In addition, introduction or the delivery for introduction of a misbranded drug into interstate commerce violates the FDCA.⁶⁴ Both criminal and civil actions may be brought against individuals or companies dispensing misbranded drugs (such as those dispensed without a valid prescription).⁶⁵

Obviously, an online pharmacy dispensing prescription drugs without a valid prescription is in violation of the FDCA.⁶⁶ The online pharmacies purporting to offer an online consultation before issuing a prescription and distributing the prescription drugs are not in violation of 21 U.S.C. § 353(b) if they are issuing a valid “prescription.” What constitutes a valid prescription in cyberspace may in fact depend upon state law.⁶⁷ It has been suggested, however, that for a prescription to be valid under 21 U.S.C. § 353(b) it must be issued in the context of a “legitimate” doctor-patient relationship.⁶⁸

⁶¹ See 21 U.S.C. § 301 et seq.

⁶² See 21 U.S.C. § 353.

⁶³ See 21 U.S.C. § 353(b)(1).

⁶⁴ See 21 U.S.C. § 331(a).

⁶⁵ See 21 U.S.C. § 333(a).

⁶⁶ See 21 U.S.C. § 353(b)(1).

⁶⁷ WORKING GROUP REPORT, *supra* note 4, at Appendix D.

⁶⁸ *Id.* (“For example, with the assistance of FDA, the Department of Justice has successfully prosecuted doctors who ‘prescribed’ steroids (which were regulated at the time as prescription drugs, rather than controlled substances, as they are now) without establishing legitimate

The Federation of State Medical Boards (“FSMB”) has stated that physicians who participate in an online operation where prescriptions are issued solely on the basis of an electronic medical questionnaire fail to meet an acceptable standard of care.⁶⁹ If such prescriptions are not valid as a matter of state or federal law, then the online pharmacy may be found to be distributing “misbranded” medication in violation of the FDCA.⁷⁰

b) _____

Federal Trade Commission Act

Online pharmacies may also be regulated under the Federal Trade Commission Act (“FTCA”).⁷¹ Websites may be enjoined for engaging in unfair or deceptive acts or practices, including false advertising of medications.⁷² Online pharmacies making false or deceptive representations to potential consumers are in violation of the FTCA, making the website operator subject to a civil enforcement action.⁷³

c) Other federal statutes

Federal mail and wire fraud statutes are applicable if an online pharmacy doctor-patient relationships with their customers.”)

⁶⁹ *Id.*

⁷⁰ *Id.*

⁷¹ 15 U.S.C. § 45 et seq.

⁷² *See id.* §§ 45(a), 52

⁷³ WORKING GROUP REPORT, *supra* note 4, at Appendix D (“For instance, claiming that a properly licensed physician will review the online questionnaire would be such a representation, as would a representation that a product is safe. Websites may represent, falsely, that medical information collected from consumers will be kept confidential or that an online consultation is equivalent to a physical examination.”).

defrauds a consumer.⁷⁴ Also, related federal criminal and civil laws may be implicated where an online pharmacy makes false representations to an insurer to obtain payment.⁷⁵

2. State

Some states, including Kansas, Missouri, Illinois, and Michigan, have sued or plan to sue online pharmacies using state consumer protection acts.⁷⁶ Such suits claim that the act of prescribing and dispensing drugs over the Internet is deceptive and unconscionable, in violation of the consumer protection act, where neither the prescriber nor the dispensing pharmacy is licensed in the consumer's state.⁷⁷ Even in a successful suit, however, a given state can only affect the operations of an online pharmacy in that state.⁷⁸ States also have jurisdiction over the licensing and regulation of physicians and prescribers operating within the state.

B.

Enforcement challenges

⁷⁴*Id.* (“Whether such a suit would be criminal or civil, under 18 U.S.C. § 1345 or the FDCA, would depend on the precise facts of the case and the evidence of fraudulent intent.”)

⁷⁵*Id.* (“Some websites offer to bill private or public health care programs or insurers for a ‘doctor’s’ advice or for the price of the drug or product itself.”)

⁷⁶*See Senate HELP Hearing, supra* note 5 (statement of Carla J. Stovall, Kansas Attorney General).

⁷⁷*See Senate HELP Hearing, supra* note 5 (statement of Carla J. Stovall, Kansas Attorney General). Under Michigan’s Consumer Protection Act, for example, “unfair, unconscionable, or deceptive” practices in trade or commerce include “Causing a probability of confusion or misunderstanding as to the source, sponsorship, approval, or certification of goods or services.” MCL § 445.903(1)(a) (1999).

⁷⁸Accordingly, NAAG is asking Congress to provide for national injunctive relief. *Senate HELP Hearing, supra* note 5 (statement of Carla J. Stovall, Kansas Attorney General).

While applicable state and federal laws may be generally adequate, the Internet presents new and significant investigatory challenges for law enforcement at all levels.⁷⁹ In particular, the Internet introduces:

the need for real-time tracing of Internet communications across traditional jurisdictional boundaries, both domestically and internationally; the need to track down sophisticated users who commit unlawful acts on the Internet while hiding their identities; the need for hand-in-glove coordination among various law enforcement agencies; and the need for trained and well-equipped personnel – at federal, state, local, and global levels – to gather evidence, investigate, and prosecute these cases.⁸⁰

The coordination of enforcement efforts at state and federal levels is a particularly daunting task. Online pharmacies that offer an online diagnosis of medical problems and provide prescriptions and distribution of prescription drugs domestically are regulated by different federal and state agencies.⁸¹ Federal statutes primarily regulate the illegal sale of prescription medications, but a state has jurisdiction over the licensing and regulation of physicians and prescribers operating within the state.⁸²

State regulators face a challenge in investigating physicians offering online consultations. First, state agencies face the potential difficulty of identifying names, locations, and any licensure or registration of the physicians and pharmacists affiliated with an online pharmacy. The time and resources necessary to pursue enforcement actions against these individuals may become prohibitive if they reside outside the state. Finally, a successful enforcement action against a given online pharmacy does not prevent the website from providing online consulta-

⁷⁹WORKING GROUP REPORT, *supra* note 4.

⁸⁰*Id.*

⁸¹*Id.*, at Appendix D.

⁸²*Id.*

tions and prescriptions drugs to consumers in other states.⁸³

The issue of foreign-based online pharmacies has the most unanswered questions and poses the greatest challenge to U.S. law enforcement.⁸⁴ The states are completely dependent upon the federal government to prevent the illegal importation of prescription drugs.⁸⁵ Unfortunately, there are no international laws upon which the United States and the Food and Drug Administration (“FDA”) can rely to take action against foreign operators.⁸⁶ As a result, FDA is dependent on the foreign country’s cooperation in taking action against the operator of an illicit website and otherwise enforcing U.S. laws pertaining to prescription drugs.⁸⁷

C. _____

Enforcement actions

1. Federal

As a result of new enforcement measures, by March 2000 FDA had more than 40 sites being actively reviewed for possible regulatory or civil action. In addition, FDA had sent 23 warning letters to domestic online drug sellers and

⁸³WORKING GROUP REPORT, *supra* note 4, at Appendix D.

⁸⁴*Senate HELP Hearing*, *supra* note 5 (statement of John Taylor, senior adviser of the Office of Regulatory Affairs of the Food and Drug Administration).

⁸⁵*Senate HELP Hearing*, *supra* note 5 (statement of Carla J. Stovall, Kansas Attorney General) (“We would appreciate aggressive enforcement of overseas companies by the DEA and Customs and others that can do that beyond what we can.”).

⁸⁶*Senate HELP Hearing*, *supra* note 5 (statement of Jane E. Henney, Food and Drug Administration Commissioner).

⁸⁷*Senate HELP Hearing*, *supra* note 5 (statement of John Taylor, senior adviser of the Office of Regulatory Affairs of the Food and Drug Administration).

transmitted “cyber letters” to thirteen operators of foreign-based websites offering prescription drugs for sale online.⁸⁸ An injunction was imposed on one product and others were being considered, including some for unapproved therapies being offered online.⁸⁹

In the year preceding the hearing, FDA also conducted eight product seizures, issued six product recalls, and incited the voluntary destruction of seven violative products.⁹⁰

With respect to actions taken against suspected criminal activity, FDA Office of Criminal Investigations currently has at least 134 open investigations of websites selling prescription drugs, providing unapproved products, or committing various types of health fraud.⁹¹ FDA also reported 36 arrests and 17 convictions related to the sale of drugs over the Internet.⁹²

In another approach, the U.S. Customs Service’s CyberSmuggling Center is working with Customs attaché offices to identify and target foreign-based online pharmacies that are shipping prescription drugs and controlled substances into the United States.⁹³ FDA does work with the U.S. Customs Service to try and prevent illegal pharmaceutical products from entering the United States,⁹⁴

⁸⁸ *Id.*

⁸⁹ The product against which an injunction has been imposed contains a “potent thyroid hormone” and was marketed as a weight loss aid. *Senate HELP Hearing*, supra note 5 (statement of John Taylor, senior adviser of the Office of Regulatory Affairs of the Food and Drug Administration).

⁹⁰ *Id.*

⁹¹ As of March 21, 2000. Fifty-four of the 134 investigations are of websites selling prescription drugs. The other 80 investigations are of websites committing health fraud or offering unapproved products for sale. *Id.*

⁹² *Id.*

⁹³ WORKING GROUP REPORT, supra note 4, at Appendix D.

⁹⁴ U.S. Customs Service reported a 450% increase in the number of seizures of illegal pharmaceutical products from 1999, an increase attributed directly to Internet sales. *Senate HELP Hearing*, supra note 5 (statement of Senator James M. Jeffords).

and has expressed its dedication to assisting Customs in detecting illegal products purchased online.⁹⁵

2. State

A small but growing number of states have taken action against illegal online pharmacies. As noted above, some states, have sued or plan to sue online pharmacies using state consumer protection acts.⁹⁶ In addition, at least twelve states have taken action against physicians for prescribing violations related to online pharmacies.⁹⁷

D.

Initiatives

1.

⁹⁵*Senate HELP Hearing*, supra note 5 (statement of John Taylor, senior adviser of the Office of Regulatory Affairs of the Food and Drug Administration).

⁹⁶For example, in December 1999, Michigan issued cease-and-desist order to ten online pharmacies. See Japsen, supra note 11. New Jersey sued eight out-of-state online pharmacies (whose websites included viagralov-making.com, ez-diet-products.com, and anydrugs.net) in March 2000 under its Consumer Fraud Act for failing to disclose they were not licensed to dispense drugs or practice medicine in the state. See Kevin G. Demarrais, *New Jersey Accuses Online Drugstores of Selling Medications Illegally*, KNIGHT-RIDDER TRIBUNE BUS. NEWS, Mar. 31, 2000.

⁹⁷At the time of the Senate HELP Hearing, they included California, Colorado, Florida, Hawaii, Illinois, Michigan, Missouri, Nevada, Ohio, Washington, Wisconsin, and Wyoming. *Senate HELP Hearing*, supra note 5 (statement of Bruce A. Levy, Executive Director of the Texas State Board of Medical Examiners). For example, the Illinois Department of Professional Regulation fined an Illinois doctor and placed him on two years of probation for writing prescriptions over the Internet without physically examining the patients. Bendavid, supra note 39. The Illinois physician, Robert Filice, issued a statement in response to the state action, saying that he was guilty only of “being a pioneer in a new and unexplored area.” Postrel, supra note 3. Arizona’s Board of Osteopathic Examiners also recently restricted the licenses of three osteopaths for prescribing Viagra and other lifestyle-changing drugs on the Internet without properly examining patients and recording their medical histories. See Della de Lafuente, *Online Drugstores Under Scrutiny*, ARIZONA REPUBLIC, Apr 30, 2000.

Federal initiatives

The House Oversight Hearing in July 1999 before the U.S. House of Representatives Senate Committee, Subcommittee on Oversight and Investigations,⁹⁸ was the first widely publicized government response to online pharmacies. Investigative journalists and representatives from online pharmacies, federal agencies, national medical and pharmacy associations, and state law enforcement presented testimony on the issues and problems related to online pharmacies.

Also in July 1999, FTC suggested that websites offering prescription drugs be required to disclose certain information about the pharmacy dispensing the medication, the states where the pharmacy is licensed to operate, personal information about the physicians providing prescriptions online, and the states to which the website will distribute prescription drugs.⁹⁹

In August 1999, President Clinton issued an executive order establishing the President's Working Group on Unlawful Conduct on the Internet ("Working Group").¹⁰⁰ The Working Group was given the task of studying unlawful activity taking place on the Internet, including the unlawful sale of prescription drugs.¹⁰¹ It released its report ("Working Group Report") on March 9, 2000.¹⁰²

Also in August 1999, Congressman Ronald Klink (D-PA) introduced the Internet Pharmacy Consumer Protection Act, H.R. 2763, which would require

⁹⁸ *House Oversight Hearing*, *supra* note 5.

⁹⁹ WORKING GROUP REPORT, *supra* note 4, at Appendix D.

¹⁰⁰ Exec. Order No. 13,133, *supra* note 4.

¹⁰¹ *Id.*

¹⁰² WORKING GROUP REPORT, *supra* note 4.

online pharmacies to provide identifying information on their websites and authorize FDA to enforce the requirements.¹⁰³ In February 2000, Representative Ronald Paul (R-TX) introduced H.R. 3636,¹⁰⁴ which included an amendment to FDCA Section 503(b).¹⁰⁵ The amendment simply clarifies the applicability of the FDCA to prescription drug purchases made through the Internet, but it would also prohibit the FDA from taking action against an Internet website for prescription drug sales, so long as the sale complied with the FDCA and applicable state law and the website displayed information regarding its compliance.¹⁰⁶

Before the Working Group Report was released, the Clinton Administration issued a policy initiative in a “Statement Announcing Zero Tolerance for Prescription Drug Internet Sites Harmful to Patient Safety and Health.”¹⁰⁷ The December 1999 initiative proposed stiff civil penalties for “rogue operators” of pharmacy websites, a mandatory federal pre-approval scheme, and a \$10 million budget to fund FDA monitoring efforts.¹⁰⁸

A well-publicized hearing before the Senate Health, Education, Labor and Pensions (“HELP”) Committee in March 2000 addressed the issue of how to develop a comprehensive scheme to regulate online pharmacies.¹⁰⁹ Many of the same representatives who testified at the House Oversight Hearing were in attendance.

In the short time between the two Congressional hearings, however, several ac-

¹⁰³H.R. 2763, 106th Cong. (1999).

¹⁰⁴H.R. 3636, 106th Cong. (1999).

¹⁰⁵21 U.S.C. 353(b).

¹⁰⁶H.R. 3636, 106th Cong. (1999).

¹⁰⁷35 Weekly Comp. Pres. Doc. 2677.

¹⁰⁸*Id.*

¹⁰⁹*Senate HELP Hearing, supra* note 5.

tions, described above, had been taken by law enforcement at both the state and federal levels. While acknowledging the difficulty of drafting legislation that will ensure the protection of the public health without stifling online business, HELP Committee member Senator Christopher Dodd concluded: “I think what is very clear is that doing nothing is not an option.”¹¹⁰ FDA Commissioner Jane Henney agreed that the consequences of government inaction or delay in the face of these challenges could include adverse side effects or loss of life.¹¹¹

By the time of the Senate HELP Hearing, FDA had taken several steps to prevent illegal sales of pharmaceuticals online. First, FDA prioritized the greatest public health threats posed by unregulated online pharmacies: sales of unapproved new drugs,¹¹² health fraud, and prescription drugs sold without a prescription.¹¹³ Second, FDA improved its technology and ability to monitor the Internet and acquire information on potentially violative sites.¹¹⁴

FDA also coordinated a “triage team” for case assessment. The team, which includes representatives from different key government agencies, is responsible for analyzing information and determining if any enforcement measures need

¹¹⁰At the same time, Dodd cautioned that the fact a hearing was being held on the “serious” and “growing” issue does not indicate that the problem is “endemic.” In fact, Dodd claimed, “the overwhelming majority of pharmacies do their business properly and well.” *Senate HELP Hearing*, supra note 5 (statement of Senator Christopher J. Dodd).

¹¹¹*Senate HELP Hearing*, supra note 5 (statement of Jane E. Henney, Food and Drug Administration Commissioner).

¹¹²Some of the products FDA is most concerned about include illegal drugs like GHB, drugs designed to treat seizures, hormones, drugs designed to treat prosthetic hypertrophy, and generally drugs that should not be used without a physician’s supervision. *See Senate HELP Hearing*, supra note 5 (statement of Janet Woodcock, Director of the Center for Drug Evaluation and Research of the Food and Drug Administration).

¹¹³*Senate HELP Hearing*, supra note 5 (statement of John Taylor, senior adviser of the Office of Regulatory Affairs of the Food and Drug Administration).

¹¹⁴*Senate HELP Hearing*, supra note 5 (statement of John Taylor, senior adviser of the Office of Regulatory Affairs of the Food and Drug Administration).

to be taken.¹¹⁵ FDA also signed agreements with the National Association of Boards of Pharmacy (“NABP”) and FSMB to work together to address the issue of illegal online prescription drug sales.¹¹⁶ According to FDA, the “team effort has eliminated overlap, increased communications and streamlined the overall enforcement process.”¹¹⁷

FDA has taken further steps to improve consumer education. Education is viewed as a critical component in the war against the illegal sale of prescription drugs over the Internet.¹¹⁸ At the Senate HELP Hearing, Senator Dodd suggested that consumers are not as careful when shopping online as when shopping offline: “Too often we assume that simply because a business has a web site, it must be legitimate.”¹¹⁹ To address this, FDA has created a website with recommendations about making purchases online.¹²⁰

2.

¹¹⁵ *Id.*

¹¹⁶ See Henkel, *supra* note 3.

¹¹⁷ *Senate HELP Hearing*, *supra* note 5 (statement of John Taylor, senior adviser of the Office of Regulatory Affairs of the Food and Drug Administration).

¹¹⁸ But there is some uncertainty as to the best approach to consumer education. During the Senate HELP Hearing, Senator Dodd asked FDA representatives why FDA has not posted a list of domestic websites on the FDA website (www.fda.gov) that the FDA has effectively “condemned” for their online activities. *Senate HELP Hearing*, *supra* note 5 (statement of Senator Christopher J. Dodd). FDA has instead taken an “opposite tack,” focusing its education efforts on providing information about the harms of particular products offered online and how consumers can identify legitimate online pharmacies. *Senate HELP Hearing*, *supra* note 5 (statement of Jane E. Henney, Food and Drug Administration Commissioner). FDA representatives at the Senate HELP Hearing also expressed a reluctance to condemn a domestic website in the manner suggested by Senator Dodd precisely because of the difficulties faced in investigating and inquiring information about suspected websites; websites “are very hard to tease apart.” *Id.* (“[W]e certainly don’t want to be wrong”).

¹¹⁹ *Senate HELP Hearing*, *supra* note 5 (statement of Senator Christopher J. Dodd).

¹²⁰ The website also contains information about the Clinton Administration initiative, enforcement actions taken by FDA against online pharmacies, and testimony of FDA officials. See U.S. Food and Drug Administration, *Buying Medical Products Online*, visited on April 29, 2000) <<http://www.fda.gov/oc/buyonline/default.htm>> (“Here’s information on how you can take advantage of the convenience and privacy of online buying while still protecting your health and your money.”).

State-based initiatives

To address the issue of “rogue” pharmacy websites, at least nine states have adopted rules or statements clarifying standards for online prescription and dispensing of medications.¹²¹ Five states have introduced legislation establishing the practice standards for prescribing drugs through the Internet.¹²²

In addition, the Special Committee on Professional Conduct and Ethics of FSMB has recommended that state medical boards “consider it unprofessional conduct by a physician, subject to disciplinary action, to provide treatment recommendations, including issuing a prescription via electronic or other means, unless the physician has performed a history and physical examination of the patient adequate to establish diagnosis and identify underlying conditions or contraindications to this treatment.”¹²³

To encourage the disclosure by online pharmacies of information about their corporation, licensure, and pharmacists, NABP has created the Verified Internet Pharmacy Practice Sites (“VIPPS”) program. Only five pharmacy websites have as yet qualified for the VIPPS “seal of approval” for meeting the program’s criteria, which include compliance with state law and voluntary compliance with

¹²¹Alabama, California, Florida, Maryland, Missouri, Nevada, North Carolina, Ohio, and Texas. *Senate HELP Hearing*, supra note 5 (statement of Bruce A. Levy, Executive Director of the Texas State Board of Medical Examiners).

¹²²Arizona, California, Florida, Kansas, and Virginia. *Senate HELP Hearing*, supra note 5 (statement of Bruce A. Levy, Executive Director of the Texas State Board of Medical Examiners).

¹²³*Senate HELP Hearing*, supra note 5 (statement of Bruce A. Levy, Executive Director of the Texas State Board of Medical Examiners).

requirements developed by NABP.¹²⁴

VI.

Proposals and criticisms

The proposals that follow all contain measures designed to combat the law enforcement challenges described above. Most contributors to this issue agree that coordination of law enforcement efforts is required, and that additional funding is required to monitor the Internet for offenders. Most also agree that consumer education is very important so that patients are discouraged from patronizing “rogue” online pharmacies. While existing federal law and state law may be adequate to regulate online pharmacies, there is general agreement that some steps must be taken to ensure that online pharmacies make disclosures or obtain appropriate certifications. As a complement to existing laws, such disclosures would offer to consumers the same verification of legitimacy that exists in the offline world, so that they can distinguish legitimate websites from the “rogue” ones.¹²⁵ The controversy, of course, is over who should regulate the disclosures.

The White House “zero tolerance” initiative focuses on increasing the existing civil penalties for illegal prescription drug sales and improving the resources

¹²⁴The recipient websites are drugstore.com, cvs.com, PlanetRx.com, medco.com, and familymeds.com. *Senate HELP Hearing*, *supra* note 5 (statement of Carmen A. Catizone, Executive Director of the National Association of Boards of Pharmacies).

¹²⁵WORKING GROUP REPORT, *supra* note 4, at Appendix D. (“Consumers are assured of the safety and suitability of the drugs that they take not only because the drugs must be prescribed by a licensed physician, but also because they must be dispensed by a licensed pharmacy.”)

available to combat illegal activity online.¹²⁶ For instance, the initiative seeks to give FDA administrative subpoena authority, which would enable FDA to investigate violative websites faster and more efficiently.¹²⁷ The initiative also proposes a public education effort aimed at consumers.

Finally, and most controversially, the White House initiative suggests establishing new federal requirements specifically for online pharmacies.¹²⁸ The White House initiative requires that online pharmacies seek FDA approval before offering online services. The pre-approval process would ensure that online pharmacies comply with all relevant state and federal laws.¹²⁹ All pharmacy websites meeting the requirements would be allowed to display a visual indicator, such as a seal of approval, that consumers could look for when shopping online.¹³⁰

The rationale behind the White House proposal is that while states have traditionally handled the regulation of pharmacies very well, a federal system of

¹²⁶Civil money penalties would increase to a maximum of \$500,000. Also, to fund FDA investigative efforts in routinely checking for illegal Internet sites, the initiative is proposing that \$10 million in new funds be allocated for fiscal year 2001. See U.S. Food and Drug Administration, *Online Pharmacies FAQs*, last modified January 27, 2000 <<http://www.fda.gov/oc/buyonline/prfaqs.html>> (“[T]he proposal provides for civil money penalties for the illegal sale of prescription drugs. Depending on the nature and severity of the violation, a person may face up to \$500,000 in civil money penalties and/or criminal sanctions.”).

¹²⁷*Id.* (“To obtain records needed for investigating suspect Websites, FDA has often had to rely on the issuance of grand jury subpoenas. This is a time-consuming process that has led to unnecessary delays in investigating potentially illegal Websites. The authority being proposed is limited in scope, but would allow FDA to acquire certain information by obtaining a subpoena administratively, thus saving precious investigative time.”).

¹²⁸The Administration plan focuses primarily on prescription drugs. Whether other FDA-regulated products (over-the-counter drugs, medical devices, etc.) will be covered is still being worked out for the legislative proposal. *Id.*

¹²⁹Appendix D (“These requirements, the details of which are undergoing interagency review, might include disclosures or certifications regarding the identity of pharmacists or other relevant health care professionals employed by the website and the states in which they are licensed.”)

¹³⁰Participation in the regulatory program will be mandatory, in contrast with the Verified Internet Pharmacy Practice Sites (VIPPS) program directed by National Association of Boards of Pharmacy (NABP). See U.S. Food and Drug Administration, *Online Pharmacies FAQs*, *supra* note 126.

credentials for Internet pharmacies is necessary to regulate the rapidly growing number of online pharmacies.¹³¹ The current regulatory scheme is based on the model of a patient visiting a local doctor or hospital, having a physician issue a prescription, and then filling the prescription at a pharmacy. Supporters of federal regulation of online pharmacies argue that the traditional model is outdated and that the laws must change to address the reality of how illegal online pharmacies operate in cyberspace.¹³² State investigators simply do not have the resources available to regulate a multiplying number of multistate operations and still provide the same level of protection that exists in the system of traditional “brick-and-mortar” pharmacies.

In any case, according to FDA representatives, the Clinton Administration initiative is not designed to preempt any state laws or encourage FDA to take more actions on its own without state involvement.¹³³ FDA does not intend to change the “long-standing policy” of working closely with state authorities “on issues that impact the practice of pharmacy or the practice of medicine, which have traditionally been regulated by the states.”¹³⁴ FDA would only step in if state action proves insufficient.¹³⁵

It is hoped by FDA Commissioner Henney that the legislative resolution of any potential jurisdictional problems would be aided by the common goal of pro-

¹³¹ See, e.g., Adams, *supra* note 2.

¹³² Bendavid, *supra* note 39 (quoting FDA spokesman Bill Hubbard: “A site in Arizona selling to 40 other states may not be something officials in Arizona care about. And officials in the 40 other states may have no way to get at it. You need a law that fits the crime, and current law does not fit the crime.”)

¹³³ See U.S. Food and Drug Administration, *Online Pharmacies FAQs*, *supra* note 126.

¹³⁴ See *id.*

¹³⁵ Bendavid, *supra* note 39. Hubbard insisted that “brick-and-mortar” pharmacies would feel no effect from the proposed measures. *Id.*

protecting the health of patients and consumers: “[I]t’s really all about outcome here.”¹³⁶ The message being presented by FDA and the Clinton Administration is crafted so the traditional authority of the states in these matters is recognized and lauded. In this spirit, Henney suggested that “what we’re striving for here is a safety net for the [online] that is strong as any that works within any state’s borders.”¹³⁷ The White House proposal, Henney said, “will be heavily reliant on what states have traditionally done, both through their enforcement [and] through the oversight of the practices in medicine and pharmacy in those states.”¹³⁸

FDA highlights the cooperative nature of its approach thus far, pointing to the formal agreements reached with NABP and FSMB and its work with NAAG.¹³⁹ FDA acknowledges that it has authority in the areas of the practice of pharmacy or the practice of medicine, but claims that it would continue to rely upon the state licensing and regulatory boards for enforcement actions.¹⁴⁰

There is evidence that efforts can be coordinated without generating crippling interjurisdictional squabbles. The Working Group Report highlights an alliance of the Kansas Attorney General’s Office and the U.S. Attorney’s Office for the District of Kansas that was formed in August 1999. The federal-state coalition included representatives from the Kansas Pharmacy Board, Kansas Board of Healing Arts, Consumer Protection Division, the Medicaid Fraud and Abuse

¹³⁶ *Senate HELP Hearing*, *supra* note 5 (statement of Jane E. Henney, Food and Drug Administration Commissioner).

¹³⁷ *Id.*

¹³⁸ *Id.*

¹³⁹ *See* U.S. Food and Drug Administration, *Online Pharmacies FAQs*, *supra* note 126.

¹⁴⁰ *Id.*

Division, and the Food and Drug Administration’s Office of Criminal Investigations.¹⁴¹

The state authorities are charged with identifying online pharmacies that may not meet state regulations but are attempting to offer legitimate pharmaceutical services. According to the Working Group, Kansas authorities have found that once notified, such operations will generally conform their conduct to meet state regulations.¹⁴² The U.S. Attorney’s Office main role is the identification of individuals responsible for illegal online pharmacy websites. Kansas state officials then take legal action against those physicians, prescribers, website operators, or pharmacies responsible for dispensing prescription drugs over the Internet in violation of Kansas state law (i.e., where “prescriptions” issued based solely on online consultations are deemed invalid”).¹⁴³

But if cooperative law enforcement efforts can work, is federal pre-approval of online pharmacies necessary? The states do not necessarily believe that the federal government should step in to regulate online pharmacies because website operations may cross state boundaries.¹⁴⁴ State law enforcement representatives at the Congressional hearings have been adamant about continuing their traditional role as the primary enforcement authority in regulating pharmacies, physicians, and generally businesses and professions that operate via the Internet. With regard to the White House proposal for requiring pre-approval of pharmacies operating online, NAAG thinks that “is a path better left untrav-

¹⁴¹WORKING GROUP REPORT, *supra* note 4, at Appendix D.

¹⁴²*Id.*

¹⁴³WORKING GROUP REPORT, *supra* note 4, at Appendix D.

¹⁴⁴*Senate HELP Hearing, supra* note 5 (statement of Carla J. Stovall, Kansas Attorney General).

eled.”¹⁴⁵

The states are fully aware, however, of their limitations in addressing the issue “rogue” online pharmacies. As discussed above, even if a state is successful in enjoining a targeted online pharmacy from conducting operations in that state, the website may continue operating in other states. Those other states would have to seek their own injunctions. To avoid this unnecessary duplication of scarce state resources, NAAG has asked Congress to provide for national injunctive relief.¹⁴⁶ With national injunctive relief, a state acting in its traditional role to protect the health of its own citizens could secure an injunction in a federal district court and also enjoin the illegitimate online pharmacy from operating throughout the United States.¹⁴⁷ At the same time, NAAG wants Congress to provide disclosure requirements in order to aid state law enforcement.¹⁴⁸

FSMB believes that current laws are adequate, “but strict and aggressive enforcement must be encouraged.”¹⁴⁹ FSMB feels that the most appropriate involvement of the federal government is in this area of “aggressive enforcement.”¹⁵⁰ In an effort to meet the investigative challenges faced by states, FSMB plans to establish a central “clearinghouse” for information regarding the operation of suspected pharmacy websites that could be accessed by all

¹⁴⁵ *Id.*

¹⁴⁶ *Id.*

¹⁴⁷ *Id.*

¹⁴⁸ *Id.* (“The difficulty that states [have] in going after these folks is to get through the multiple layers of shell corporations to get to the fake addresses, the different layers that are involved to try to hide the true identities.”).

¹⁴⁹ *Senate HELP Hearing*, supra note 5 (statement of Bruce A. Levy, Executive Director of the Texas State Board of Medical Examiners).

¹⁵⁰ *Id.*

state medical boards.¹⁵¹

Reaction to the Clinton Administration's initiative from the industry was mixed.¹⁵²

Pharmacy groups expressed their belief that any additional regulation by FDA would create an unnecessary barrier to electronic commerce.¹⁵³ Fearing increased regulation by FDA, the industry felt that the states, which were already involved in investigating suspect Internet websites, should be allowed to continue in their traditional role of regulating pharmacies.¹⁵⁴ Some industry groups also feared that special measures created for the Internet could eventually lead to similar regulation of mail-order pharmacies.¹⁵⁵

Some retail pharmacies and mail-order drug firms, however, expressed approval of Administration's proposal to require online pharmacies to get federal approval before dispensing medications online.¹⁵⁶ Some major retail pharmacies would prefer federal regulation of their online operations because it might bolster consumer confidence in the pharmacy industry generally.¹⁵⁷

The National Association of Chain Drug Stores ("NACDS") expressed its approval of the Administration's goal, but supports the continuation of NABP's voluntary VIPPS program.¹⁵⁸ It contends that voluntary measures like VIPPS,

¹⁵¹ *Id.*

¹⁵² *See, e.g.,* Adams, *supra* note 2.

¹⁵³ *See id.* (quoting Susan Winckler, a policy director for the American Pharmaceutical Association: "I don't know that the FDA jumping in and regulating will bring any benefit. It will just confuse the situation."). Shares in some online drugstore companies dropped in response to the proposed increase in federal oversight. *See id.*

¹⁵⁴ *See id.*

¹⁵⁵ *See id.*

¹⁵⁶ *See* Bruce Japsen, *supra* note 11 (quoting David Joyner, senior vice president of sales and marketing for the prescription division of Caremark Rx Inc.: "We're in line with Clinton on this.").

¹⁵⁷ *Id.* (quoting Michael Polzin, spokesman for Walgreen Co.: "It doesn't overly concern us that the FDA would be looking to get involved. But we would like to work with them to draft their standards.").

¹⁵⁸ *See* Sherman Fridman, *NACDS Urges Caution in Internet Drug Regulation*, NEWSBYTES

when coupled with NABP oversight and more aggressive enforcement of already existing regulations by FDA, state boards of pharmacy, and state boards of medicine, are adequate to protect consumers “without the expansion of the FDA’s authority over the legitimate practice of pharmacy.”¹⁵⁹

On the other hand, the National Community Pharmacists Association (“NCPA”) supports a federal requirement that all Internet pharmacies verify and also disclose on their websites their state licensure and the licensure of their pharmacists.¹⁶⁰ NCPA also supports penalties for pharmacies and pharmacists selling prescription medication without a valid prescription.¹⁶¹ A “significant” new initiative is not necessary, however. Instead, NCPA recommends that existing laws be used in conjunction with cooperative efforts by state and federal agencies.¹⁶²

One area in which there is little direction concerns how the United States should address the issue of prescription drugs being imported illegally from abroad. Notably, there is no specific mention of foreign-based websites in the White House proposal. One avenue of attack may be to rely more heavily on the foreign counterparts to the U.S. Customs Service and FDA to deal with online prescription firms in other countries.¹⁶³ Unfortunately, the “philosophical differences between countries on combating the sale of illegal goods online” often thwart efforts at such cooperation.¹⁶⁴

NEWS NETWORK, available at 1999 WL 29944400, December 29, 1999.

¹⁵⁹ *Id.* (quoting Craig L. Fuller, president and chief executive officer of NACDS).

¹⁶⁰ *Senate HELP Hearing*, *supra* note 5 (statement of Calvin A. Anthony, executive vice president of National Community Pharmacists Association).

¹⁶¹ *Id.*

¹⁶² *Id.*

¹⁶³ WORKING GROUP REPORT, *supra* note 4, at Appendix D.

¹⁶⁴ *Id.*

However, while many parcels entering the United States are being seized by the Customs Service,¹⁶⁵ “the Customs Service and the FDA would require a substantial increase in resources and personnel as a practical matter to stop all, or even most, illegal prescription drugs from entering the country.”¹⁶⁶ The \$10 million in new funding requested in the White House initiative for fiscal year 2001 likely would not be applied by FDA to efforts like interception of illegally imported drugs.¹⁶⁷

In another approach, NABP is trying to convince some other countries to adopt VIPPS program in order to create “an international safety net” for consumers of prescriptions drugs online.¹⁶⁸

Finally, to complicate the matter further, some commentators anticipate that successful regulation and enforcement efforts domestically will merely force illegitimate operations abroad.¹⁶⁹

VII.

Conclusion

The recent media and Congressional attention given to the issue of illegal

¹⁶⁵See WORKING GROUP REPORT, *supra* note 4, at Appendix D. (“Upon a determination by FDA that the drugs are in violation of law, the parcels are seized and referred for investigative follow-up. The Customs Service seized 9,725 packages with prescription drugs last year, over four times as many as were seized in 1998.”)

¹⁶⁶*Id.*

¹⁶⁷The funding is apparently to be allocated for staff and resources necessary to monitor domestic websites. *Senate HELP Hearing*, *supra* note 5 (statement of Jane E. Henney, Food and Drug Administration Commissioner) (“In terms of working the foreign issue in specific, that [requested funding] would not permit us to totally increase that effort. Again, we’re highly reliant on the relationships that we’ve got with other countries if we’re going to be effective in that area.”).

¹⁶⁸*Senate HELP Hearing*, *supra* note 5 (statement of Carla J. Stovall, Kansas Attorney General).

¹⁶⁹See *id.*

sales of prescription drugs online highlight the threat to public health posed by “rogue” online pharmacies and the challenges faced by state and federal law enforcement. State and federal agencies are starting to coordinate their efforts and will likely improve this approach over time. Some states, though limited in financial and technological resources, have taken action against “rogue” pharmacies. All parties to the issue seem to agree that disclosure is the key to establishing and affirming the legitimacy of pharmacy websites, but the terms of a disclosure program still need to be worked out. The biggest challenge in regulating the illegal sale of prescription drugs online remains the issue of how to address the fact that many of the “rogue” online pharmacies are foreign-based.

FDA Commissioner Henney characterized the required response to the threat to public health as “a long-haul effort.” At the Senate HELP Hearing, Henney reiterated FDA’s dedication to the project and said FDA is attempting “to engage all parties that have an interest in making this work right for the American public,” including state boards of healing arts, state boards of pharmacy, and state attorneys general.¹⁷⁰ Still, FDA representatives and committee members both expressed concern that the level of issue focus and priority represented by the Working Group report and the Senate HELP Hearing would fade.¹⁷¹

¹⁷⁰ *Senate HELP Hearing*, supra note 5 (statement of Jane E. Henney, Food and Drug Administration Commissioner).

¹⁷¹ *See, e.g., Senate HELP Hearing*, supra note 5 (statement of Senator Christopher J. Dodd) (“A lot of times these reports, they end up – they’re wonderful reports, they end up sitting on a shelf, obviously, as we’ve seen far too often.”). The concern may be well-founded. On May 2, 2000, the White House sent a bill containing the details of its “zero tolerance” policy to Congress without fanfare and with little media attention. *See Reaction Mixed To Administration Bill On Web Drug Sales*, NATIONAL JOURNAL’S CONGRESSDAILY, May 4, 2000.